



What is informed consent?

- Informed consent is the process of learning important facts about the research study before you decide whether or not to volunteer. If you agree to volunteer, it should be based on a clear understanding of what will take place in the study and how it might affect you.
- Informed consent begins when the research staff explains the study to you. These facts include details about the study, tests or procedures you may receive, the benefits and risks that could result, and your rights as a research volunteer.
- Once your questions have been answered and you fully understand the facts about the research study, you will be asked to sign an “informed consent form”. You should take your time when you read the informed consent form. If you have any questions, ask the research staff to explain.



What if I do not want to take part in a research study?

- If anyone asks you to take part in a research study, you have the right to say “no.”
- Your decision will not affect your VA health care or benefits.
- You need to weigh both the risks of the study and the benefits.
- It may be helpful to talk with family members, friends or your health care providers before you make a decision.
- If you decide to take part in a study, you do so as a **VOLUNTEER**. This means **YOU** decide.
- You can change your mind and stop or leave a research study at any time without losing any of your VA health care benefits.

If you have any questions, concerns, or complaints about VA research, or if you would like to talk to someone about the VA research program, please contact your local Research & Development office at:

COACH Center On Advice
& Compliance Help
Helping VA facilities protect veterans in research
www.research.va.gov/programs/PRIDE

Volunteering in RESEARCH



Here are
some things
you need
to know



Department of
Veterans Affairs



What is a research study?

A research study is an organized activity to learn more about a problem or answer a question. A research study may be done to:

- Understand health needs, problems, or feelings people have about an illness or their general health
- Test if a product, such as a drug or equipment, is safe and effective
- Determine the best way to treat an illness, or how to prevent an illness
- Find out what health care practices work best

One specific type of research study is a clinical trial. A clinical trial is a medical study that tries to determine whether medicines, new therapies or new devices are safe and effective. In a clinical trial, a drug or treatment is often compared to a placebo (an inactive substance given as if it were a therapy, but typically has no value to treat or prevent an illness).



What questions should I ask before volunteering?

Here are some questions you might ask before deciding to take part in a research study at a VA Medical Center or clinic:

- ☐ Who is doing this study and what questions might it answer?
- ☐ Who reviewed or approved this study?
- ☐ How long will this study last?
- ☐ What could happen to me, good or bad, if I take part in this study?
- ☐ What tests or procedures will I have during the study?
- ☐ Who will be told I am taking part in this study?
- ☐ Will this research help in understanding my condition? If so, how?
- ☐ Is it possible that I will receive a placebo (inactive substance)?
- ☐ What happens to any specimens that I give?
- ☐ Could my condition get worse during the study? What happens if it does?
- ☐ What other options or choices do I have if I decide not to take part in this study?
- ☐ Who will be in charge of my care? Can I continue seeing my own doctor?
- ☐ Will I be charged anything or paid anything to be in this study?
- ☐ If I decide to participate, how will it affect my daily life?
- ☐ Will I have to make extra trips to the VA?
- ☐ What will happen to me at the end of the study?
- ☐ Will I be told the results of the study?
- ☐ How do I end my participation in this study if I change my mind?
- ☐ Whom do I contact for questions and information about the study?